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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,121	07/02/2003	Jamie L. Brewer	260385.20005	6561
7590	07/13/2006			EXAMINER
Eugene LeDonne, Esq Reed Smith, LLP 599 Lexington Avenue, 29th Floor New York, NY 10022				JUEDES, AMY E
				ART UNIT PAPER NUMBER
				1644

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/612,121	BREWER ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Amy E. Juedes, Ph.D.	1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 April 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.  
 4a) Of the above claim(s) 1-14, 17 and 18 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 15 and 16 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/7/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____ .                                  |

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**DETAILED ACTION**

1. Applicant's election without traverse of group IV, claims 15-16, drawn to a kit comprising SEQ ID Nos: 33-55, in the reply filed on 4/24/06 is acknowledged.

Claims 1-14 and 17-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 15-16 read on the elected invention and are being acted upon.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spinella et al., 1994 (of record), in view of Wei et al., 1994 and US patent 6,017,699.

Spinella et al. teach that analysis of TCR gene expression, particularly by PCR, is becoming increasingly important to a variety of clinical programs (see pg. 111 in particular). Spinella et al. further teach employing a standard reference template in the PCR that consists of cloned TCR genes of the 24 known TCR V $\beta$  families (i.e. V $\beta$  1-24, see pg. 114 and Fig. 9.3, in particular). Spinella et al. further teach that including the reference templates is extremely important since it helps to ensure the accuracy of the analysis (see pg. 115, in particular). Furthermore, said reference template comprising the cloned genes of V $\beta$ 1-V $\beta$ 24 would comprise SEQ ID NO: 33-54, since these represent DNA fragments derived from V $\beta$ 1-V $\beta$ 24 TCR V regions.

Spinella et al. do not teach the TCRV $\beta$ 25 gene, or a kit comprising the reference templates, an enzyme, buffer solutions, and deoxynucleotide triphosphates.

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Wei et al. teach the identification of a new TCRV $\beta$  gene segment, V $\beta$ 25 (see Fig. 1 in particular).

The '699 patent teaches that reagents necessary for performing an assay can be packaged in a kit as a matter of convenience (see column 6 in particular). The '699 patent also teaches that kits can comprise quantification reagents, including PCR reagents such as buffers, enzymes, and nucleoside triphosphates (see column 7 in particular).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add the gene encoding the TCR V $\beta$ 25 region, as taught by Wei et al., to the standard reference template set comprising the TCR V $\beta$ 1-24 genes taught by Spinella et al. The ordinary artisan at the time the invention was made would have been motivated to do so, since Spinella et al. teach that a reference template comprising the V $\beta$  genes of all the known V $\beta$  families is extremely important since it helps to ensure the accuracy of TCR analysis, and Wei et al. teach that V $\beta$ 25 is a newly identified TCR V $\beta$  gene. Furthermore, the ordinary artisan would have been motivated to package the reagents necessary for performing the PCR reaction (an enzyme, buffers, and deoxynucleotide triphosphates), as taught by the '699 patent, along with the reference template made obvious by Spinella et al. and Wei et al. The ordinary artisan at the time the invention was made would have been motivated to do so since the '699 patent teaches that reagents necessary for performing an assay can be packaged in a kit as a matter of convenience. Furthermore, said reference template comprising the cloned genes of V $\beta$ 1-V $\beta$ 25 would comprise SEQ ID NO: 33-55, since these represent DNA fragments derived from V $\beta$ 1-V $\beta$ 25 TCR V regions.

4. No claim is allowed.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the

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organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy E. Juedes, Ph.D.  
Patent Examiner  
Technology Center 1600  
June 22, 2006

  
7/1/06  
**G.R. EWOLDT, PH.D.**  
**PRIMARY EXAMINER**